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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,904	03/29/2006	Lars Bjorck	053694-0131	7961

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,904	BJORCK ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 29-47 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 29-37 drawn to a method for identifying an anti-streptococcal agent, which method comprises: (a) providing, as a first component, an isolated streptococcal M protein or a functional variant thereof; (b) providing, as a second component, isolated fibrinogen or a functional variant thereof; (c) providing, as a third component, an isolated .E-backward..sub.2 integrin or a functional variant thereof; (d) contacting said components with a test substance under conditions that would permit the components to interact in the absence of the test substance; and (e) determining whether the test substance inhibits the interaction between the components; thereby to determine whether a test substance is an anti-streptococcal agent or

(f) providing, as a first component, a streptococcal M protein or a functional variant thereof; (g) providing, as a second component, fibrinogen or a functional variant thereof; (h) providing, as a third component, one or more polymorphonuclear neutrophils (PMNs); (i) contacting said components with a test substance under conditions that would permit the components to interact

in the absence of the test substance; and (j) monitoring any inhibition of the activation of PMNs; thereby to determine whether a test substance is an anti-streptococcal agent.

Group II, claim(s) 38-40, drawn to a test kit comprising: (a) an isolated streptococcal M protein or a functional variant thereof; (b) isolated fibrinogen or a functional variant thereof; and (c) an isolated beta 2 integrin or a functional variant thereof; wherein said test kit is suitable for use in identifying a test substance which is capable of inhibiting the interaction between a streptococcal M protein or a functional variant thereof, fibrinogen and a functional variant thereof and a .beta..sub.2 integrin or a functional variant thereof or a test kit comprising: (d) a streptococcal M protein or a functional variant thereof; (e) fibrinogen or a functional variant thereof; and (f) one or more PMNs; wherein said test kit is suitable for use in identifying a test substance which is capable of inhibiting the interaction between a streptococcal M protein or a functional variant thereof, fibrinogen or a functional variant thereof and PMNs.

Group III, claim(s) 41 and 46 drawn to an anti-streptococcal agent

Group IV, claim(s) 42-45, drawn to a method of treating an individual suffering from a streptococcal infection.

Group V, claim(s) 47, drawn to a method for providing a pharmaceutical composition, which method comprises: (a) identifying an agent that inhibits the interaction between streptococcal M

protein, fibrinogen and beta 2 integrin by a method according to claim 29; and (b) formulating the inhibitor thus identified with a pharmaceutically acceptable carrier or diluent.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Method of treatment with, *select from*:

- anti-integrin antibody,
- a peptide mimetic of an integrin antagonist
- a non-peptide mimetic of an integrin antagonist
- GPRP
- antibody which specifically binds the repeats of *S. pyogenes* M1 protein

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, claim 42 is generic to the above species.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The first appearing technical feature of group I is a method for identifying an anti-streptococcal agent, which method comprises: (a) providing, as a first component, an isolated streptococcal M protein or a functional variant thereof; (b) providing, as a second component, isolated fibrinogen or a functional variant thereof; (c) providing, as a third component, an isolated beta 2 integrin or a functional variant thereof; (d) contacting said components with a test substance under conditions that would permit the components to interact in the absence of the test substance; and (e) determining whether the test substance inhibits the interaction between the components; thereby to determine whether a test substance is an anti-streptococcal agent or (f) providing, as a first component, a streptococcal M protein or a functional variant thereof; (g) providing, as a second component, fibrinogen or a functional variant thereof; (h) providing, as a third component, one or more polymorphonuclear neutrophils (PMNs); (i) contacting said components with a test substance under conditions that would permit the components to interact in the absence of the test substance; and (j) monitoring any inhibition of the activation of PMNs; thereby to determine whether a test substance is an anti-streptococcal agent.
- The second technical feature in group II is a test kit comprising: (a) an isolated streptococcal M protein or a functional variant thereof; (b) isolated fibrinogen or a

functional variant thereof; and (c) an isolated beta 2 integrin or a functional variant thereof or one or more PMN

- The third technical feature in group III is an anti-streptococcal agent.
- The fourth technical feature in Group IV is a method of treatment with an anti-streptococcal agent.
- The fourth technical feature of Group V is an anti-streptococcal agent.

The technical feature linking groups I-V is an anti-streptococcal agent that inhibits the interaction between M protein, fibrinogen and beta2 integrin/neutrophil. This technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Cue et al (PNAS vol. 97: p. 2858-2863, March 2000, cited in IDS) who teaches a non-peptide integrin antagonist that can be used for treatment of streptococcal infections. Thus, Groups I to V lacks unity.

As to the species set forth above, Cue et al (PNAS 2000 March 14; 97(6): 2858-2863, cited in IDS) teaches the use of non peptide integrin antagonists to enhance the efficacy of antibiotics in treatment of *S. pyogenes*. Thus, the common technical feature linking the methods i.e. a method of treating with an anti-streptococcal agent is taught by Cue et al and is therefore not a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.
If attempts to reach the examiner by telephone are unsuccessful, either of the examiner's supervisors Shanon Foley (571-272-0898) or Robert Mondesi (571-272-0956) can be contacted. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645